

§ 170.315 2015 Edition health IT certification criteria.

The Secretary adopts the following certification criteria for health IT. Health IT must be able to electronically perform the following capabilities in accordance with all applicable standards and implementation specifications adopted in this part:

(a) *Clinical*—(1) *Computerized provider order entry—medications*. (i) Enable a user to record, change, and access medication orders.

(ii) *Optional*. Include a “reason for order” field.

(2) *Computerized provider order entry—laboratory*. (i) Enable a user to record, change, and access laboratory orders.

(ii) *Optional*. Include a “reason for order” field.

(3) *Computerized provider order entry—diagnostic imaging*. (i) Enable a user to record, change, and access diagnostic imaging orders.

(ii) *Optional*. Include a “reason for order” field.

(4) *Drug-drug, drug-allergy interaction checks for CPOE*—(i) *Interventions*. Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically indicate to a user drug-drug and drug-allergy contraindications based on a patient’s medication list and medication allergy list.

(ii) *Adjustments*. (A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.

(B) Limit the ability to adjust severity levels in at least one of these two ways:

(1) To a specific set of identified users.

(2) As a system administrative function.

(5) *Demographics*. (i) Enable a user to record, change, and access patient demographic data including race, ethnicity, preferred language, sex, sexual orientation, gender identity, and date of birth.

(A) *Race and ethnicity*. (1) Enable each one of a patient’s races to be recorded in accordance with, at a minimum, the standard specified in §170.207(f)(2) and whether a patient declines to specify race.

(2) Enable each one of a patient’s ethnicities to be recorded in accordance with, at a minimum, the standard specified in §170.207(f)(2) and whether a patient declines to specify ethnicity.

(3) Aggregate each one of the patient’s races and ethnicities recorded in accordance with paragraphs (a)(5)(i)(A)(1) and (2) of this section to the categories in the standard specified in §170.207(f)(1).

(B) *Preferred language*. Enable preferred language to be recorded in accordance with the standard specified in §170.207(g)(2) and whether a patient declines to specify a preferred language.

(C) *Sex*. Enable sex to be recorded in accordance with the standard specified in §170.207(n)(1).

(D) *Sexual orientation*. Enable sexual orientation to be recorded in accordance with the standard specified in §170.207(o)(1) and whether a patient declines to specify sexual orientation.

(E) *Gender identity*. Enable gender identity to be recorded in accordance with the standard specified in §170.207(o)(2) and whether a patient declines to specify gender identity.

(ii) *Inpatient setting only*. Enable a user to record, change, and access the preliminary cause of death and date of death in the event of mortality.

(6) *Problem list*. Enable a user to record, change, and access a patient’s active problem list:

(i) *Ambulatory setting only*. Over multiple encounters in accordance with, at a minimum, the version of the standard specified in §170.207(a)(4).

(ii) *Inpatient setting only*. For the duration of an entire hospitalization in accordance with, at a minimum, the version of the standard specified in §170.207(a)(4).

(7) *Medication list*. Enable a user to record, change, and access a patient’s active medication list as well as medication history:

(i) *Ambulatory setting only*. Over multiple encounters.

(ii) *Inpatient setting only*. For the duration of an entire hospitalization.

(8) *Medication allergy list*. Enable a user to record, change, and access a patient’s active medication allergy list as well as medication allergy history:

(i) *Ambulatory setting only*. Over multiple encounters.

(ii) *Inpatient setting only.* For the duration of an entire hospitalization.

(9) *Clinical decision support (CDS)*—(i) *CDS intervention interaction.* Interventions provided to a user must occur when a user is interacting with technology.

(ii) *CDS configuration.* (A) Enable interventions and reference resources specified in paragraphs (a)(9)(iii) and (iv) of this section to be configured by a limited set of identified users (*e.g.*, system administrator) based on a user's role.

(B) Enable interventions:

(1) Based on the following data:

(i) Problem list;

(ii) Medication list;

(iii) Medication allergy list;

(iv) At least one demographic specified in paragraph (a)(5)(i) of this section;

(v) Laboratory tests; and

(vi) Vital signs.

(2) When a patient's medications, medication allergies, and problems are incorporated from a transition of care/referral summary received and pursuant to paragraph (b)(2)(iii)(D) of this section.

(iii) *Evidence-based decision support interventions.* Enable a limited set of identified users to select (*i.e.*, activate) electronic CDS interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the data referenced in paragraphs (a)(9)(ii)(B)(1)(i) through (vi) of this section.

(iv) *Linked referential CDS.* (A) Identify for a user diagnostic and therapeutic reference information in accordance at least one of the following standards and implementation specifications:

(1) The standard and implementation specifications specified in § 170.204(b)(3).

(2) The standard and implementation specifications specified in § 170.204(b)(4).

(B) For paragraph (a)(9)(iv)(A) of this section, technology must be able to identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the data referenced in paragraphs (a)(9)(ii)(B)(1)(i), (ii), and (iv) of this section.

(v) *Source attributes.* Enable a user to review the attributes as indicated for all CDS resources:

(A) For evidence-based decision support interventions under paragraph (a)(9)(iii) of this section:

(1) Bibliographic citation of the intervention (clinical research/guideline);

(2) Developer of the intervention (translation from clinical research/guideline);

(3) Funding source of the intervention development technical implementation; and

(4) Release and, if applicable, revision date(s) of the intervention or reference source.

(B) For linked referential CDS in paragraph (a)(9)(iv) of this section and drug-drug, drug-allergy interaction checks in paragraph (a)(4) of this section, the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).

(10) *Drug-formulary and preferred drug list checks.* The requirements specified in one of the following paragraphs (that is, paragraphs (a)(10)(i) and (a)(10)(ii) of this section) must be met to satisfy this certification criterion:

(i) *Drug formulary checks.* Automatically check whether a drug formulary exists for a given patient and medication.

(ii) *Preferred drug list checks.* Automatically check whether a preferred drug list exists for a given patient and medication.

(11) *Smoking status.* Enable a user to record, change, and access the smoking status of a patient.

(12) *Family health history.* Enable a user to record, change, and access a patient's family health history in accordance with the familial concepts or expressions included in, at a minimum, the version of the standard in § 170.207(a)(4).

(13) *Patient-specific education resources.* (i) Identify patient-specific education resources based on data included in the patient's problem list and medication list in accordance with at least one of the following standards and implementation specifications:

(A) The standard and implementation specifications specified in § 170.204(b)(3).

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(B) The standard and implementation specifications specified in § 170.204(b)(4).

(ii) *Optional.* Request that patient-specific education resources be identified in accordance with the standard in § 170.207(g)(2).

(14) *Implantable device list.* (i) Record Unique Device Identifiers associated with a patient's Implantable Devices.

(ii) Parse the following identifiers from a Unique Device Identifier:

(A) Device Identifier; and

(B) The following identifiers that compose the Production Identifier:

(1) The lot or batch within which a device was manufactured;

(2) The serial number of a specific device;

(3) The expiration date of a specific device;

(4) The date a specific device was manufactured; and

(5) For an HCT/P regulated as a device, the distinct identification code required by 21 CFR 1271.290(c).

(iii) Obtain and associate with each Unique Device Identifier:

(A) A description of the implantable device referenced by at least one of the following:

(1) The "GMDN PT Name" attribute associated with the Device Identifier in the Global Unique Device Identification Database.

(2) The "SNOMED CT® Description" mapped to the attribute referenced in paragraph (a)(14)(iii)(A)(1) of this section.

(B) The following Global Unique Device Identification Database attributes:

(1) "Brand Name";

(2) "Version or Model";

(3) "Company Name";

(4) "What MRI safety information does the labeling contain?"; and

(5) "Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)."

(iv) Display to a user an implantable device list consisting of:

(A) The active Unique Device Identifiers recorded for the patient;

(B) For each active Unique Device Identifier recorded for a patient, the description of the implantable device specified by paragraph (a)(14)(iii)(A) of this section; and

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(C) A method to access all Unique Device Identifiers recorded for a patient.

(v) For each Unique Device Identifier recorded for a patient, enable a user to access:

(A) The Unique Device Identifier;

(B) The description of the implantable device specified by paragraph (a)(14)(iii)(A) of this section;

(C) The identifiers associated with the Unique Device Identifier, as specified by paragraph (a)(14)(ii) of this section; and

(D) The attributes associated with the Unique Device Identifier, as specified by paragraph (a)(14)(iii)(B) of this section.

(vi) Enable a user to change the status of a Unique Device Identifier recorded for a patient.

(15) *Social, psychological, and behavioral data.* Enable a user to record, change, and access the following patient social, psychological, and behavioral data:

(i) *Financial resource strain.* Enable financial resource strain to be recorded in accordance with the standard specified in § 170.207(p)(1) and whether a patient declines to specify financial resource strain.

(ii) *Education.* Enable education to be recorded in accordance with the standard specified in § 170.207(p)(2) and whether a patient declines to specify education.

(iii) *Stress.* Enable stress to be recorded in accordance with the standard specified in § 170.207(p)(3) and whether a patient declines to specify stress.

(iv) *Depression.* Enable depression to be recorded in accordance with the standard specified in § 170.207(p)(4) and whether a patient declines to specify depression.

(v) *Physical activity.* Enable physical activity to be recorded in accordance with the standard specified in § 170.207(p)(5) and whether a patient declines to specify physical activity.

(vi) *Alcohol use.* Enable alcohol use to be recorded in accordance with the standard specified in § 170.207(p)(6) and whether a patient declines to specify alcohol use.

(vii) *Social connection and isolation.* Enable social connection and isolation to be recorded in accordance with the standard specified in § 170.207(p)(7) and

whether a patient declines to specify social connection and isolation.

(viii) *Exposure to violence (intimate partner violence)*. Enable exposure to violence (intimate partner violence) to be recorded in accordance with the standard specified in § 170.207(p)(8) and whether a patient declines to specify exposure to violence (intimate partner violence).

(b) *Care coordination*—(1) *Transitions of care*—(i) *Send and receive via edge protocol*—(A) Send transition of care/referral summaries through a method that conforms to the standard specified in § 170.202(d) and that leads to such summaries being processed by a service that has implemented the standard specified in § 170.202(a)(2); and

(B) Receive transition of care/referral summaries through a method that conforms to the standard specified in § 170.202(d) from a service that has implemented the standard specified in § 170.202(a)(2).

(C) *XDM processing*. Receive and make available the contents of a XDM package formatted in accordance with the standard adopted in § 170.205(p)(1) when the technology is also being certified using an SMTP-based edge protocol.

(ii) *Validate and display*—(A) *Validate C-CDA conformance—system performance*. Demonstrate the ability to detect valid and invalid transition of care/referral summaries received and formatted in accordance with the standards specified in § 170.205(a)(3) and § 170.205(a)(4) for the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates. This includes the ability to:

(1) Parse each of the document types.
(2) Detect errors in corresponding “document-templates,” “section-templates,” and “entry-templates,” including invalid vocabulary standards and codes not specified in the standards adopted in § 170.205(a)(3) and § 170.205(a)(4).

(3) Identify valid document-templates and process the data elements required in the corresponding section-templates and entry-templates from the standards adopted in § 170.205(a)(3) and § 170.205(a)(4).

(4) Correctly interpret empty sections and null combinations.

(5) Record errors encountered and allow a user through at least one of the following ways to:

(i) Be notified of the errors produced.
(ii) Review the errors produced.

(B) *Display*. Display in human readable format the data included in transition of care/referral summaries received and formatted according to the standards specified in § 170.205(a)(3) and § 170.205(a)(4).

(C) *Display section views*. Allow for the individual display of each section (and the accompanying document header information) that is included in a transition of care/referral summary received and formatted in accordance with the standards adopted in § 170.205(a)(3) and § 170.205(a)(4) in a manner that enables the user to:

(1) Directly display only the data within a particular section;
(2) Set a preference for the display order of specific sections; and
(3) Set the initial quantity of sections to be displayed.

(iii) *Create*. Enable a user to create a transition of care/referral summary formatted in accordance with the standard specified in § 170.205(a)(4) using the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates that includes, at a minimum:

(A) The Common Clinical Data Set.

(B) *Encounter diagnoses*. Formatted according to at least one of the following standards:

(1) The standard specified in § 170.207(i).

(2) At a minimum, the version of the standard specified in § 170.207(a)(4).

(C) Cognitive status.

(D) Functional status.

(E) *Ambulatory setting only*. The reason for referral; and referring or transitioning provider's name and office contact information.

(F) *Inpatient setting only*. Discharge instructions.

(G) *Patient matching data*. First name, last name, previous name, middle name (including middle initial), suffix, date of birth, address, phone number, and sex. The following constraints apply:

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(1) *Date of birth constraint*—(i) The year, month and day of birth must be present for a date of birth. The technology must include a null value when the date of birth is unknown.

(ii) *Optional*. When the hour, minute, and second are associated with a date of birth the technology must demonstrate that the correct time zone offset is included.

(2) *Phone number constraint*. Represent phone number (home, business, cell) in accordance with the standards adopted in §170.207(q)(1). All phone numbers must be included when multiple phone numbers are present.

(3) *Sex constraint*. Represent sex in accordance with the standard adopted in §170.207(n)(1).

(2) *Clinical information reconciliation and incorporation*—(i) *General requirements*. Paragraphs (b)(2)(ii) and (iii) of this section must be completed based on the receipt of a transition of care/referral summary formatted in accordance with the standards adopted in §170.205(a)(3) and §170.205(a)(4) using the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates.

(ii) *Correct patient*. Upon receipt of a transition of care/referral summary formatted according to the standards adopted §170.205(a)(3) and §170.205(a)(4), technology must be able to demonstrate that the transition of care/referral summary received can be properly matched to the correct patient.

(iii) *Reconciliation*. Enable a user to reconcile the data that represent a patient's active medication list, medication allergy list, and problem list as follows. For each list type:

(A) Simultaneously display (*i.e.*, in a single view) the data from at least two sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date.

(B) Enable a user to create a single reconciled list of each of the following: Medications; medication allergies; and problems.

(C) Enable a user to review and validate the accuracy of a final set of data.

(D) Upon a user's confirmation, automatically update the list, and incor-

porate the following data expressed according to the specified standard(s):

(1) *Medications*. At a minimum, the version of the standard specified in §170.207(d)(3);

(2) *Medication allergies*. At a minimum, the version of the standard specified in §170.207(d)(3); and

(3) *Problems*. At a minimum, the version of the standard specified in §170.207(a)(4).

(iv) *System verification*. Based on the data reconciled and incorporated, the technology must be able to create a file formatted according to the standard specified in §170.205(a)(4) using the Continuity of Care Document document template.

(3) *Electronic prescribing*. (i) Enable a user to perform all of the following prescription-related electronic transactions in accordance with the standard specified in §170.205(b)(2) and, at a minimum, the version of the standard specified in §170.207(d)(3) as follows:

(A) Create new prescriptions (NEWRX).

(B) Change prescriptions (RXCHG, CHGRES).

(C) Cancel prescriptions (CANRX, CANRES).

(D) Refill prescriptions (REFREQ, REFRES).

(E) Receive fill status notifications (RXFILL).

(F) Request and receive medication history information (RXHREQ, RXHRES).

(ii) For each transaction listed in paragraph (b)(3)(i) of this section, the technology must be able to receive and transmit the reason for the prescription using the diagnosis elements in DRU Segment.

(iii) *Optional*. For each transaction listed in paragraph (b)(3)(i) of this section, the technology must be able to receive and transmit the reason for the prescription using the indication elements in the SIG Segment.

(iv) Limit a user's ability to prescribe all oral liquid medications in only metric standard units of mL (*i.e.*, not cc).

(v) Always insert leading zeroes before the decimal point for amounts less than one and must not allow trailing zeroes after a decimal point when a user prescribes medications.

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(4) *Common Clinical Data Set summary record—create*. Enable a user to create a transition of care/referral summary formatted in accordance with the standard specified in § 170.205(a)(4) using the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates that includes, at a minimum:

- (i) The Common Clinical Data Set.
- (ii) *Encounter diagnoses*. Formatted according to at least one of the following standards:
 - (A) The standard specified in § 170.207(i).
 - (B) At a minimum, the version of the standard specified in § 170.207(a)(4).
 - (iii) Cognitive status.
 - (iv) Functional status.
 - (v) *Ambulatory setting only*. The reason for referral; and referring or transitioning provider's name and office contact information.
 - (vi) *Inpatient setting only*. Discharge instructions.
 - (vii) *Patient matching data*. First name, last name, previous name, middle name (including middle initial), suffix, date of birth, address, phone number, and sex. The following constraints apply:

(A) *Date of birth constraint*—(1) The year, month and day of birth must be present for a date of birth. The technology must include a null value when the date of birth is unknown.

(2) *Optional*. When the hour, minute, and second are associated with a date of birth the technology must demonstrate that the correct time zone offset is included.

(B) *Phone number constraint*. Represent phone number (home, business, cell) in accordance with the standards adopted in § 170.207(q)(1). All phone numbers must be included when multiple phone numbers are present.

(C) *Sex constraint*. Represent sex in accordance with the standard adopted in § 170.207(n)(1).

(5) *Common Clinical Data Set summary record—receive*—(i) Enable a user to receive a transition of care/referral summary formatted in accordance with the standards adopted in § 170.205(a)(3) and § 170.205(a)(4) using the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Sum-

mary document templates that includes, at a minimum:

- (A) The Common Clinical Data Set.
- (B) *Encounter diagnoses*. Formatted according to at least one of the following standards:
 - (1) The standard specified in § 170.207(i).
 - (2) At a minimum, the standard specified in § 170.207(a)(4).
 - (C) Cognitive status.
 - (D) Functional status.
 - (E) *Ambulatory setting only*. The reason for referral; and referring or transitioning provider's name and office contact information.
 - (F) *Inpatient setting only*. Discharge instructions.

(ii) *Validate and display*. Demonstrate the following functionalities for the document received in accordance with paragraph (b)(5)(i) of this section:

(A) *Validate C-CDA conformance—system performance*. Detect valid and invalid transition of care/referral summaries including the ability to:

(1) Parse each of the document types formatted according to the following document templates: Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary.

(2) Detect errors in corresponding “document-templates,” “section-templates,” and “entry-templates,” including invalid vocabulary standards and codes not specified in the standards adopted in § 170.205(a)(3) and § 170.205(a)(4).

(3) Identify valid document-templates and process the data elements required in the corresponding section-templates and entry-templates from the standards adopted in § 170.205(a)(3) and § 170.205(a)(4).

(4) Correctly interpret empty sections and null combinations.

(5) Record errors encountered and allow a user through at least one of the following ways to:

- (i) Be notified of the errors produced.
- (ii) Review the errors produced.

(B) *Display*. Display in human readable format the data included in transition of care/referral summaries received and formatted according to the standards specified in § 170.205(a)(3) and § 170.205(a)(4).

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(C) *Display section views.* Allow for the individual display of each section (and the accompanying document header information) that is included in a transition of care/referral summary received and formatted in accordance with the standards adopted in § 170.205(a)(3) and § 170.205(a)(4) in a manner that enables the user to:

(1) Directly display only the data within a particular section;

(2) Set a preference for the display order of specific sections; and

(3) Set the initial quantity of sections to be displayed.

(6) *Data export*—(i) *General requirements for export summary configuration.*

(A) Enable a user to set the configuration options specified in paragraphs (b)(6)(iii) and (iv) of this section when creating an export summary as well as a set of export summaries for patients whose information is stored in the technology. A user must be able to execute these capabilities at any time the user chooses and without subsequent developer assistance to operate.

(B) Limit the ability of users who can create export summaries in at least one of these two ways:

(1) To a specific set of identified users.

(2) As a system administrative function.

(ii) *Creation.* Enable a user to create export summaries formatted in accordance with the standard specified in § 170.205(a)(4) using the Continuity of Care Document document template that includes, at a minimum:

(A) The Common Clinical Data Set.

(B) *Encounter diagnoses.* Formatted according to at least one of the following standards:

(1) The standard specified in § 170.207(i).

(2) At a minimum, the version of the standard specified in § 170.207(a)(4).

(C) Cognitive status.

(D) Functional status.

(E) *Ambulatory setting only.* The reason for referral; and referring or transitioning provider's name and office contact information.

(F) *Inpatient setting only.* Discharge instructions.

(iii) *Timeframe configuration.* (A) Enable a user to set the date and time period within which data would be used

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to create the export summaries. This must include the ability to enter in a start and end date and time range.

(B) Consistent with the date and time period specified in paragraph (b)(6)(iii)(A) of this section, enable a user to do each of the following:

(1) Create export summaries in real-time;

(2) Create export summaries based on a relative date and time (e.g., the first of every month at 1:00 a.m.); and

(3) Create export summaries based on a specific date and time (e.g., on 10/24/2015 at 1:00 a.m.).

(iv) *Location configuration.* Enable a user to set the storage location to which the export summary or export summaries are intended to be saved.

(7) *Data segmentation for privacy—send.* Enable a user to create a summary record formatted in accordance with the standard adopted in § 170.205(a)(4) that is document-level tagged as restricted and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1).

(8) *Data segmentation for privacy—receive.* Enable a user to:

(i) Receive a summary record that is formatted in accordance with the standard adopted in § 170.205(a)(4) that is document-level tagged as restricted and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1);

(ii) Sequester the document-level tagged document from other documents received; and

(iii) View the restricted document without incorporating any of the data from the document.

(9) *Care plan.* Enable a user to record, change, access, create, and receive care plan information in accordance with the Care Plan document template, including the Health Status Evaluations and Outcomes Section and Interventions Section (V2), in the standard specified in § 170.205(a)(4).

(c) *Clinical quality measures*—(1) *Clinical quality measures—record and export*—(i) *Record.* For each and every CQM for which the technology is presented for certification, the technology must be able to record all of the data that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified

entries, which may include specific terms as defined by each CQM, or may include codified expressions of “patient reason,” “system reason,” or “medical reason.”

(ii) *Export*. A user must be able to export a data file at any time the user chooses and without subsequent developer assistance to operate:

(A) Formatted in accordance with the standard specified in § 170.205(h)(2);

(B) Ranging from one to multiple patients; and

(C) That includes all of the data captured for each and every CQM to which technology was certified under paragraph (c)(1)(i) of this section.

(2) *Clinical quality measures—import and calculate*—(i) *Import*. Enable a user to import a data file in accordance with the standard specified in § 170.205(h)(2) for one or multiple patients and use such data to perform the capability specified in paragraph (c)(2)(ii) of this section. A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.

(ii) Calculate each and every clinical quality measure for which it is presented for certification.

(3) *Clinical quality measures—report*. Enable a user to electronically create a data file for transmission of clinical quality measurement data:

(i) At a minimum, in accordance with the standards specified in § 170.205(h)(2) and § 170.205(k)(1) and (2).

(ii) *Optional*. That can be electronically accepted by CMS.

(4) *Clinical quality measures—filter*. (i) Record the data listed in paragraph (c)(4)(iii) of this section in accordance with the identified standards, where specified.

(ii) Filter CQM results at the patient and aggregate levels by each one and any combination of the data listed in paragraph (c)(4)(iii) of this section and be able to:

(A) Create a data file of the filtered data in accordance with the standards adopted in § 170.205(h)(2) and § 170.205(k)(1) and (2); and

(B) Display the filtered data results in human readable format.

(iii) *Data*.

(A) Taxpayer Identification Number.

(B) National Provider Identifier.

(C) Provider type in accordance with, at a minimum, the standard specified in § 170.207(r)(1).

(D) Practice site address.

(E) Patient insurance in accordance with the standard specified in § 170.207(s)(1).

(F) Patient age.

(G) Patient sex in accordance with the version of the standard specified in § 170.207(n)(1).

(H) Patient race and ethnicity in accordance with, at a minimum, the version of the standard specified in § 170.207(f)(2).

(I) Patient problem list data in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4).

(d) *Privacy and security*—(1) *Authentication, access control, and authorization*. (i) Verify against a unique identifier(s) (e.g., username or number) that a user seeking access to electronic health information is the one claimed; and

(ii) Establish the type of access to electronic health information a user is permitted based on the unique identifier(s) provided in paragraph (d)(1)(i) of this section, and the actions the user is permitted to perform with the technology.

(2) *Auditable events and tamper-resistance*—(i) *Record actions*. Technology must be able to:

(A) Record actions related to electronic health information in accordance with the standard specified in § 170.210(e)(1);

(B) Record the audit log status (enabled or disabled) in accordance with the standard specified in § 170.210(e)(2) unless it cannot be disabled by any user; and

(C) Record the encryption status (enabled or disabled) of electronic health information locally stored on end-user devices by technology in accordance with the standard specified in § 170.210(e)(3) unless the technology prevents electronic health information from being locally stored on end-user devices (see paragraph (d)(7) of this section).

(ii) *Default setting*. Technology must be set by default to perform the capabilities specified in paragraph

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(d)(2)(i)(A) of this section and, where applicable, paragraphs (d)(2)(i)(B) and (d)(2)(i)(C) of this section.

(iii) *When disabling the audit log is permitted.* For each capability specified in paragraphs (d)(2)(i)(A) through (C) of this section that technology permits to be disabled, the ability to do so must be restricted to a limited set of users.

(iv) *Audit log protection.* Actions and statuses recorded in accordance with paragraph (d)(2)(i) of this section must not be capable of being changed, overwritten, or deleted by the technology.

(v) *Detection.* Technology must be able to detect whether the audit log has been altered.

(3) *Audit report(s).* Enable a user to create an audit report for a specific time period and to sort entries in the audit log according to each of the data specified in the standards in § 170.210(e).

(4) *Amendments.* Enable a user to select the record affected by a patient's request for amendment and perform the capabilities specified in paragraph (d)(4)(i) or (ii) of this section.

(i) *Accepted amendment.* For an accepted amendment, append the amendment to the affected record or include a link that indicates the amendment's location.

(ii) *Denied amendment.* For a denied amendment, at a minimum, append the request and denial of the request in at least one of the following ways:

(A) To the affected record.

(B) Include a link that indicates this information's location.

(5) *Automatic access time-out.* (i) Automatically stop user access to health information after a predetermined period of inactivity.

(ii) Require user authentication in order to resume or regain the access that was stopped.

(6) *Emergency access.* Permit an identified set of users to access electronic health information during an emergency.

(7) *End-user device encryption.* The requirements specified in one of the following paragraphs (that is, paragraphs (d)(7)(i) and (d)(7)(ii) of this section) must be met to satisfy this certification criterion.

(i) Technology that is designed to locally store electronic health information on end-user devices must encrypt

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the electronic health information stored on such devices after use of the technology on those devices stops.

(A) Electronic health information that is stored must be encrypted in accordance with the standard specified in § 170.210(a)(2).

(B) *Default setting.* Technology must be set by default to perform this capability and, unless this configuration cannot be disabled by any user, the ability to change the configuration must be restricted to a limited set of identified users.

(ii) Technology is designed to prevent electronic health information from being locally stored on end-user devices after use of the technology on those devices stops.

(8) *Integrity.* (i) Create a message digest in accordance with the standard specified in § 170.210(c)(2).

(ii) Verify in accordance with the standard specified in § 170.210(c)(2) upon receipt of electronically exchanged health information that such information has not been altered.

(9) *Trusted connection.* Establish a trusted connection using one of the following methods:

(i) *Message-level.* Encrypt and integrity protect message contents in accordance with the standards specified in § 170.210(a)(2) and (c)(2).

(ii) *Transport-level.* Use a trusted connection in accordance with the standards specified in § 170.210(a)(2) and (c)(2).

(10) *Auditing actions on health information.* (i) By default, be set to record actions related to electronic health information in accordance with the standard specified in § 170.210(e)(1).

(ii) If technology permits auditing to be disabled, the ability to do so must be restricted to a limited set of users.

(iii) Actions recorded related to electronic health information must not be capable of being changed, overwritten, or deleted by the technology.

(iv) Technology must be able to detect whether the audit log has been altered.

(11) *Accounting of disclosures.* Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in § 170.210(d).

(e) *Patient engagement*—(1) *View, download, and transmit to 3rd party.* (i) Patients (and their authorized representatives) must be able to use internet-based technology to view, download, and transmit their health information to a 3rd party in the manner specified below. Such access must be consistent and in accordance with the standard adopted in § 170.204(a)(1) and may alternatively be demonstrated in accordance with the standard specified in § 170.204(a)(2).

(A) *View.* Patients (and their authorized representatives) must be able to use health IT to view, at a minimum, the following data:

(1) The Common Clinical Data Set (which should be in their English (*i.e.*, non-coded) representation if they associate with a vocabulary/code set).

(2) *Ambulatory setting only.* Provider's name and office contact information.

(3) *Inpatient setting only.* Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization.

(4) *Laboratory test report(s).* Laboratory test report(s), including:

(i) The information for a test report as specified all the data specified in 42 CFR 493.1291(c)(1) through (7);

(ii) The information related to reference intervals or normal values as specified in 42 CFR 493.1291(d); and

(iii) The information for corrected reports as specified in 42 CFR 493.1291(k)(2).

(5) Diagnostic image report(s).

(B) *Download.* (1) Patients (and their authorized representatives) must be able to use technology to download an ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) in the following formats:

(i) Human readable format; and

(ii) The format specified in accordance to the standard specified in § 170.205(a)(4) following the CCD document template.

(2) When downloaded according to the standard specified in § 170.205(a)(4) following the CCD document template, the ambulatory summary or inpatient summary must include, at a minimum, the following data (which, for the human readable version, should be in

their English representation if they associate with a vocabulary/code set):

(i) *Ambulatory setting only.* All of the data specified in paragraph (e)(1)(i)(A)(1), (2), (4), and (5) of this section.

(ii) *Inpatient setting only.* All of the data specified in paragraphs (e)(1)(i)(A)(1), and (3) through (5) of this section.

(3) *Inpatient setting only.* Patients (and their authorized representatives) must be able to download transition of care/referral summaries that were created as a result of a transition of care (pursuant to the capability expressed in the certification criterion specified in paragraph (b)(1) of this section).

(C) *Transmit to third party.* Patients (and their authorized representatives) must be able to:

(1) Transmit the ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) created in paragraph (e)(1)(i)(B)(2) of this section in accordance with both of the following ways:

(i) Email transmission to any email address; and

(ii) An encrypted method of electronic transmission.

(2) *Inpatient setting only.* Transmit transition of care/referral summaries (as a result of a transition of care/referral as referenced by (e)(1)(i)(B)(3)) of this section selected by the patient (or their authorized representative) in both of the ways referenced (e)(1)(i)(C)(1)(i) and (ii) of this section).

(D) *Timeframe selection.* With respect to the data available to view, download, and transmit as referenced paragraphs (e)(1)(i)(A), (B), and (C) of this section, patients (and their authorized representatives) must be able to:

(1) Select data associated with a specific date (to be viewed, downloaded, or transmitted); and

(2) Select data within an identified date range (to be viewed, downloaded, or transmitted).

(ii) *Activity history log.* (A) When any of the capabilities included in paragraphs (e)(1)(i)(A) through (C) of this

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section are used, the following information must be recorded and made accessible to the patient (or his/her authorized representative):

(1) The action(s) (*i.e.*, view, download, transmission) that occurred;

(2) The date and time each action occurred in accordance with the standard specified in § 170.210(g);

(3) The user who took the action; and

(4) Where applicable, the addressee to whom an ambulatory summary or inpatient summary was transmitted.

(B) Technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) of this section if it is also certified to the certification criterion specified in § 170.315(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) of this section is accessible by the patient (or his/her authorized representative).

(2) *Secure messaging.* Enable a user to send messages to, and receive messages from, a patient in a secure manner.

(3) *Patient health information capture.* Enable a user to:

(i) Identify, record, and access information directly and electronically shared by a patient (or authorized representative).

(ii) Reference and link to patient health information documents.

(f) *Public health—(1) Transmission to immunization registries.* (i) Create immunization information for electronic transmission in accordance with:

(A) The standard and applicable implementation specifications specified in § 170.205(e)(4).

(B) At a minimum, the version of the standard specified in § 170.207(e)(3) for historical vaccines.

(C) At a minimum, the version of the standard specified in § 170.207(e)(4) for administered vaccines.

(ii) Enable a user to request, access, and display a patient's evaluated immunization history and the immunization forecast from an immunization registry in accordance with the standard at § 170.205(e)(4).

(2) *Transmission to public health agencies—syndromic surveillance.* Create syndrome-based public health surveillance information for electronic transmission in accordance with the standard (and applicable implementation

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specifications) specified in § 170.205(d)(4).

(3) *Transmission to public health agencies—reportable laboratory tests and values/results.* Create reportable laboratory tests and values/results for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(g).

(ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (c)(2).

(4) *Transmission to cancer registries.* Create cancer case information for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(i)(2).

(ii) At a minimum, the versions of the standards specified in § 170.207(a)(4) and (c)(3).

(5) *Transmission to public health agencies—electronic case reporting.* (i) Consume and maintain a table of trigger codes to determine which encounters may be reportable.

(ii) Match a patient visit or encounter to the trigger code based on the parameters of the trigger code table.

(iii) *Case report creation.* Create a case report for electronic transmission:

(A) Based on a matched trigger from paragraph (f)(5)(ii).

(B) That includes, at a minimum:

(1) The Common Clinical Data Set.

(2) *Encounter diagnoses.* Formatted according to at least one of the following standards:

(i) The standard specified in § 170.207(i).

(ii) At a minimum, the version of the standard specified in § 170.207(a)(4).

(3) The provider's name, office contact information, and reason for visit.

(4) An identifier representing the row and version of the trigger table that triggered the case report.

(6) *Transmission to public health agencies—antimicrobial use and resistance reporting.* Create antimicrobial use and resistance reporting information for electronic transmission in accordance with the standard specified in § 170.205(r)(1).

(7) *Transmission to public health agencies—health care surveys.* Create health

care survey information for electronic transmission in accordance with the standard specified in § 170.205(s)(1).

(g) *Design and performance*—(1) *Automated numerator recording*. For each EHR Incentive Programs percentage-based measure, technology must be able to create a report or file that enables a user to review the patients or actions that would make the patient or action eligible to be included in the measure's numerator. The information in the report or file created must be of sufficient detail such that it enables a user to match those patients or actions to meet the measure's denominator limitations when necessary to generate an accurate percentage.

(2) *Automated measure calculation*. For each EHR Incentive Programs percentage-based measure that is supported by a capability included in a technology, record the numerator and denominator and create a report including the numerator, denominator, and resulting percentage associated with each applicable measure.

(3) *Safety-enhanced design*. (i) User-centered design processes must be applied to each capability technology includes that is specified in the following certification criteria: Paragraphs (a)(1) through (9) and (14), (b)(2) and (3) of this section.

(ii) *Number of test participants*. A minimum of 10 test participants must be used for the testing of each capability identified in paragraph (g)(3)(i) of this section.

(iii) One of the following must be submitted on the user-centered design processed used:

(A) Name, description and citation (URL and/or publication citation) for an industry or federal government standard.

(B) Name the process(es), provide an outline of the process(es), a short description of the process(es), and an explanation of the reason(s) why use of any of the existing user-centered design standards was impractical.

(iv) The following information/sections from NISTIR 7742 must be submitted for each capability to which user-centered design processes were applied:

(A) Name and product version; date and location of the test; test environ-

ment; description of the intended users; and total number of participants;

(B) Description of participants, including: Sex; age; education; occupation/role; professional experience; computer experience; and product experience;

(C) Description of the user tasks that were tested and association of each task to corresponding certification criteria;

(D) The specific metrics captured during the testing of each user task performed in (g)(3)(iv)(C) of this section, which must include: Task success (%); task failures (%); task standard deviations (%); task performance time; and user satisfaction rating (based on a scale with 1 as very difficult and 5 as very easy) or an alternative acceptable user satisfaction measure;

(E) Test results for each task using the metrics identified above in paragraph (g)(3)(iv)(D) of this section; and

(F) Results and data analysis narrative, including: Major test finding; effectiveness; efficiency; satisfaction; and areas for improvement.

(v) Submit test scenarios used in summative usability testing.

(4) *Quality management system*. (i) For each capability that a technology includes and for which that capability's certification is sought, the use of a Quality Management System (QMS) in the development, testing, implementation, and maintenance of that capability must be identified that satisfies one of the following ways:

(A) The QMS used is established by the Federal government or a standards developing organization.

(B) The QMS used is mapped to one or more QMS established by the Federal government or standards developing organization(s).

(ii) When a single QMS was used for applicable capabilities, it would only need to be identified once.

(iii) When different QMS were applied to specific capabilities, each QMS applied would need to be identified.

(5) *Accessibility-centered design*. For each capability that a Health IT Module includes and for which that capability's certification is sought, the

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use of a health IT accessibility-centered design standard or law in the development, testing, implementation and maintenance of that capability must be identified.

(i) When a single accessibility-centered design standard or law was used for applicable capabilities, it would only need to be identified once.

(ii) When different accessibility-centered design standards and laws were applied to specific capabilities, each accessibility-centered design standard or law applied would need to be identified. This would include the application of an accessibility-centered design standard or law to some capabilities and none to others.

(iii) When no accessibility-centered design standard or law was applied to all applicable capabilities such a response is acceptable to satisfy this certification criterion.

(6) *Consolidated CDA creation performance.* The following technical and performance outcomes must be demonstrated related to Consolidated CDA creation. The capabilities required under paragraphs (g)(6)(i) through (iv) of this section can be demonstrated in tandem and do not need to be individually addressed in isolation or sequentially. This certification criterion's scope includes only data expressed within the Common Clinical Data Set definition.

(i) *Reference C-CDA match.* Create a data file formatted in accordance with the standard adopted in §170.205(a)(4) that matches a gold-standard, reference data file.

(ii) *Document-template conformance.* Create a data file formatted in accordance with the standard adopted in §170.205(a)(4) that demonstrates a valid implementation of each document template applicable to the certification criterion or criteria within the scope of the certificate sought.

(iii) *Vocabulary conformance.* Create a data file formatted in accordance with the standard adopted in §170.205(a)(4) that demonstrates the required vocabulary standards (and value sets) are properly implemented.

(iv) *Completeness verification.* Create a data file for each of the applicable document templates referenced in paragraph (g)(6)(ii) of this section without

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the omission of any of the data included in the Common Clinical Data Set definition.

(7) *Application access—patient selection.* The following technical outcome and conditions must be met through the demonstration of an application programming interface (API).

(i) *Functional requirement.* The technology must be able to receive a request with sufficient information to uniquely identify a patient and return an ID or other token that can be used by an application to subsequently execute requests for that patient's data.

(ii) *Documentation—(A)* The API must include accompanying documentation that contains, at a minimum:

(1) API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.

(2) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s).

(3) *Terms of use.* The terms of use for the API must be provided, including, at a minimum, any associated developer policies and required developer agreements.

(B) The documentation used to meet paragraph (g)(7)(ii)(A) of this section must be available via a publicly accessible hyperlink.

(8) *Application access—data category request.* The following technical outcome and conditions must be met through the demonstration of an application programming interface.

(i) *Functional requirements.* (A) Respond to requests for patient data (based on an ID or other token) for each of the individual data categories specified in the Common Clinical Data Set and return the full set of data for that data category (according to the specified standards, where applicable) in a computable format.

(B) Respond to requests for patient data associated with a specific date as well as requests for patient data within a specified date range.

(ii) *Documentation—(A)* The API must include accompanying documentation that contains, at a minimum:

(1) API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.

(2) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s).

(3) *Terms of use.* The terms of use for the API must be provided, including, at a minimum, any associated developer policies and required developer agreements.

(B) The documentation used to meet paragraph (g)(8)(ii)(A) of this section must be available via a publicly accessible hyperlink.

(9) *Application access—all data request.* The following technical outcome and conditions must be met through the demonstration of an application programming interface.

(i) *Functional requirements.* (A) Respond to requests for patient data (based on an ID or other token) for all of the data categories specified in the Common Clinical Data Set at one time and return such data (according to the specified standards, where applicable) in a summary record formatted according to the standard specified in § 170.205(a)(4) following the CCD document template.

(B) Respond to requests for patient data associated with a specific date as well as requests for patient data within a specified date range.

(ii) *Documentation.*—(A) The API must include accompanying documentation that contains, at a minimum:

(1) API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.

(2) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s).

(3) *Terms of use.* The terms of use for the API must be provided, including, at a minimum, any associated developer policies and required developer agreements.

(B) The documentation used to meet paragraph (g)(9)(ii)(A) of this section must be available via a publicly accessible hyperlink.

(h) *Transport methods and other protocols*—(1) *Direct Project*—(i) *Applicability Statement for Secure Health Transport.* Able to send and receive health information in accordance with the standard specified in § 170.202(a)(2), including formatted only as a “wrapped” message.

(ii) *Delivery Notification in Direct.* Able to send and receive health information in accordance with the standard specified in § 170.202(e)(1).

(2) *Direct Project, Edge Protocol, and XDR/XDM*—(i) Able to send and receive health information in accordance with:

(A) The standard specified in § 170.202(a)(2), including formatted only as a “wrapped” message;

(B) The standard specified in § 170.202(b), including support for both limited and full XDS metadata profiles; and

(C) Both edge protocol methods specified by the standard in § 170.202(d).

(ii) *Delivery Notification in Direct.* Able to send and receive health information in accordance with the standard specified in § 170.202(e)(1).

[80 FR 62747, Oct. 16, 2015, as amended at 80 FR 76871, Dec. 11, 2015]

Subpart D [Reserved]

Subpart E—ONC Health IT Certification Program

SOURCE: 76 FR 1325, Dec. 7, 2011, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to subpart E of part 170 appear at 80 FR 62755, Oct. 16, 2015.

§ 170.500 Basis and scope.

This subpart implements section 3001(c)(5) of the Public Health Service Act and sets forth the rules and procedures related to the ONC Health IT Certification Program for health information technology (health IT) administered by the National Coordinator for Health Information Technology.

[76 FR 1325, Dec. 7, 2011, as amended at 77 FR 54291, Sept. 4, 2012]